

REMARKS

Claims 2-5, 7-28, 30, 34-36, 42-43, 45, 47, and 54 are pending. Claims 1, 6, 29, 31-33, 37-41, 44, 46, 48-53 have been canceled without prejudice and without acquiescence. Claim 7 was made into an independent claim. Claims 2-5, 8-11, 13-14, 19, 20, 27-28, 30, 36, 42, 47 have been amended to correct claim dependency. Support for claim 54 can be found in page 12, line 24-35. Applicants assert that no new matter has been added. Applicants reserve the right to pursue amended and or canceled material in other prosecution.

The issues outstanding in this application are as follows:

- Claim 48 is objected to as containing a typographical error.
- Claims 1-53 have been rejected under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement.
- Claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 have been rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as anticipated in view of Amigo.
- Claim 7 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of the provided English translation of Zimmer *et al.*
- Claim 9 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Regnier *et al.*
- Claims 12, 13, and 29 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Karger *et al.*
- Claims 14 and 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Bergstrom *et al.*
- Claims 15-17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Malmsten *et al.*

- Claims 1 and 27 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Karger *et al.* in view of Van Alstine *et al.*
- Claim 1 and 30 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Regnier *et al.* in view of Amigo.
- Claims 42, 43, 47-49, 52 and 53 were rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. patent 5,935,401 to Amigo (herein referred to as Amigo).
- Claims 44-46 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Deacher *et al.*
- Claim 50 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Karger *et al.*
- Claim 51 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Zimmer *et al.*

Applicant respectfully traverse the outstanding objections and rejections, and applicant respectfully request reconsideration and withdrawal thereof in light of the amendments and remarks contained herein.

II. Claim Objection

This rejection is now moot in view of the cancellation of claim 48.

III. 35 USC 112, first paragraph

Claims 1-53 are rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the written description requirement. The applicants respectfully traverse.

In order to advance the prosecution of the present application, Applicants have amended the claims to remove the limitation of “non-electrophoresis.” In view of this

amendment, Applicants assert that this rejection is now moot, and respectfully request that it be withdrawn.

IV. Issues under 35 U.S.C. § 102

A. Claims 1-6, 8, 11, 18-23, 31-36 and 38-41

Claims 1-6, 8, 10, 11, 18-23, 28, 31-36, and 38-41 are rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. patent 5,935,401 to Amigo (herein referred to as Amigo). The applicants respectfully traverse.

In order to advance the prosecution of the present invention, Applicants have canceled independent claim 1 without prejudice and without acquiescence. Dependent claim 7, which is not rejected under 35 U.S.C. § 102, has been made into an independent claim and the dependent claims now depend from claim 7. Thus, Applicants assert that this rejection is now moot.

In view of the above arguments, Applicants respectfully request that the rejection be withdrawn.

B. Claims 42, 43, 47-49, 52 and 53

Claims 42, 43, 47-49, 52 and 53 are rejected under 35 U.S.C. §102(e) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over U.S. patent 5,935,401 to Amigo (herein referred to as Amigo). The applicants respectfully traverse.

In order to advance the prosecution of this application, Applicants have canceled claims 48, 49, 52 and 53 without prejudice and without acquiescence. Thus, this rejection is now moot, and Applicants respectfully request that the rejection be withdrawn.

As previously indicated, independent claim 1 was canceled without prejudice and without acquiescence. Claims 42, 43, and 47 now depend from independent claim 7, which was not rejected. Thus, these dependent claims incorporate all the limitations of independent claim 7, and the Amigo patent is precluded from anticipating the present depending claims

since it does not disclose all the limitations of independent claim 7. Thus, Applicants assert that this rejection is now moot, and respectfully request removal of this rejection.

V. Issues under 35 U.S.C. § 103

A. Claim 7

Dependent claim 7 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of the provided English translation of DE 197 53 847 (herein referred to as Zimmer). The applicants respectfully traverse.

First and foremost, the present references relied upon by the Examiner clearly fail to establish a *prima facie* case of obviousness.

As established by *In re Royka*, *prima facie* obviousness of a claimed invention can only be established if all the claim limitations are taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Examiner has failed to show that all the claimed limitations are taught or suggested by the cited references. In particular, none of the references mention a device that is in a dry state capable of being rehydrated or a device having a volume defining unit, mixing cavity, or waste cavity. If the Examiner continues to maintain that Amigo and Zimmer are the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in either Amigo or Zimmer. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Turning to the references, the Examiner appears to rely upon Zimmer to provide the suggestion that one of skill in the art would combine the device of Amigo with the disclosure mentioned in Zimmer because Zimmer mentions capillaries with sufficiently hydrophilic surfaces that draw in aqueous materials upon contact. In the Advisory Action, the Examiner has continued to misunderstand the fact that Zimmer, if anything, teaches away from the combination of self-sucking and reduced non-specific adsorption. The surface chemistry mentioned by Zimmer uses oxidized aluminum (page 9, line 1, and examples) as the preferred surface material. This surface material is inherently prone to non-specific adsorption. The other materials mentioned by Zimmer are mentioned generally (i.e.,

photoreactive hydrophilic polymer), thus, it is impossible to draw any conclusion about their ability for non-specific adsorption. Since the preferred surface materials, oxidized aluminum, of Zimmer are inherently prone to high non-specific adsorption, it would not be obvious to one of skill in the art to exchange Amigo's surfaces of low non-specific adsorption for Zimmer's hydrophilic self-sucking surfaces that in preferred variants are known to have a high non-specific adsorption. Thus, if teaching anything about non-specific adsorption, Zimmer at least inherently teaches self-sucking capillaries with inner surfaces that have a high non-specific adsorption. This is the opposite to what is desired in the cited passage of Amigo. The impropriety of combining Amigo and Zimmer is further supported by the fact that a key feature of Amigo is transport by electrophoresis or electroosmosis and if this transport is replaced by Zimmer's self-suction, Amigo's device no longer would function in the way intended. Thus, Applicants assert that the Examiner is using impermissible "hindsight" to express motivation to combine the references of Amigo and Zimmer. *See In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

Still further, Applicants can not find a suggestion or teaching of a microfluidic device defined by independent claim 7. Thus, if the Examiner maintains the rejection, the courts have required that the Examiner show some suggestion or motivation, excluding the invention itself, to make the new combination. *See In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Lee* 277 F. 2d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); and *c.f. Ruiz v. A.B. Chance Co.*, F.3d 1270 (Fed. Cir. 2004).

In conclusion, Applicants respectfully request that the rejection be withdrawn.

B. Claim 9

Claim 9 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of U.S. patent 5,958,202 to Regnier *et al.* (herein referred to as Regnier) The applicants respectfully traverse.

The Examiner has failed to establish a *prima facie* case of obviousness.

As established by *In re Royka*, *prima facie* obviousness of a claimed invention can only be established if all the claim limitations are taught or suggested by the prior art. *In re*

Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Examiner has failed to show that all the claimed limitations are taught or suggested by the cited references. In particular, none of the references mention a device that is in a dry state capable of being rehydrated, and a device having functional parts, for example, a volume defining unit, mixing cavity, or waste cavity. If the Examiner continues to maintain that Amigo and Regnier are the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in either Amigo or Regnier. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Turning to the references, the Examiner appears to rely upon the passage in Column 37, lines 53-59, to provide some suggestion of the use of non-electrokinetic means. This passage in Regnier discloses methods of “introducing” a sample or reactant volumes into the system, it does not mention or suggest “transport” of solutes within a microchannel. Applicants respectfully remind the Examiner that section 103 requires consideration of the claimed invention “as a whole.” This “as a whole” requirement prevents evaluation of the invention part by part, in hindsight. *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698 (Fed. Cir. 1983). It appears that the Examiner has combined the Amigo et al. with Reigner merely because Reigner mentions the word “electrokinetic” together with a number of injection methods that are not electrokinetic. The mere mention of a word that is part of a word in the claim, does not provide a suggest to combine with Amigo nor does it provide any expectation of success if combined. Thus, if the Examiner maintains this rejection, Examiner must show some suggestion or motivation, excluding the invention itself, to make the new combination. See *In re Rouffet*, 149 F.3d 1350, 1355-56 (Fed. Cir. 1998); *In re Lee* 277 F. 2d 1338, 61 USPQ 2d 1430 (Fed. Cir. 2002); and c.f. *Ruiz v. A.B. Chance Co.*, F.3d 1270 (Fed. Cir. 2004).

In conclusion, Applicants assert that the Examiner has not established a *prima facie* case of obviousness and respectfully request that the rejection be withdrawn.

C. Claims 12, 13 and 29

Claims 12, 13, and 29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of U.S. Patent 5,840,388 to Karger *et al.*(herein referred to as Karger) The applicants respectfully traverse.

The Examiner has failed to establish a *prima facie* case of obviousness.

As established by *In re Royka*, *prima facie* obviousness of a claimed invention can only be established if all the claim limitations are taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). The Examiner has failed to show that all the claimed limitations are taught or suggested by the cited references. In particular, none of the references mention a device having a volume defining unit, mixing cavity, or waste cavity. The references also do not mention a device having a hydrophilized surface on at least one of its functional parts for liquid to enter the part by self-suction. If the Examiner continues to maintain that Amigo and Karger are the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in either Amigo or Karger. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000). Since both these references alone, or in combination, fail to teach or suggest all the limitations of independent claim 7, as well as dependent claims 12 and 13, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49). Thus, Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

D. Claims 14 and 24-26

Claims 14 and 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of U.S. patent 5,250,613 to Bergstrom *et al.* (herein referred to as Bergstrom). The applicants respectfully traverse.

Regarding dependent claims 14, and 24-26, if an independent claim is non-obvious under 35 U.S.C. 103(a), then any claim depending therefrom is by definition non-obvious. *In re Fine*, 5 USPQ 2d 2596 (Fed. Cir. 1988). Dependent claims 14, and 24-26 depend from independent claim 7 and, thus contain all the limitations of the independent claim and are non-obvious.

Applicants assert that none of the references mention a device that is in a dry state capable of being rehydrated, or a device having a volume defining unit, mixing cavity, or waste cavity. Since both these references alone, or in combination, fail to teach or suggest all

the limitations of dependent claims 14, and 24-26, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49).

Thus, a *prima facie* case of obviousness has not been established, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

E. Claims 15-17

Claims 15-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Malmsten et al. The applicants respectfully traverse.

Regarding dependent claims 15-17, if an independent claim is non-obvious under 35 U.S.C. 103(a), then any claim depending therefrom is by definition non-obvious. *In re Fine*, 5 USPQ 2d 2596 (Fed. Cir. 1988). Dependent claims 15-17 depend from independent claim 7 and, thus contain all the limitations of the independent claim and are non-obvious.

Applicants assert that none of the references mention a device that is in a dry state capable of being rehydrated, or a device having a volume defining unit, mixing cavity, or waste cavity. Since both these references alone, or in combination, fail to teach or suggest all the limitations of dependent claims 15-17, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49).

Thus, a *prima facie* case of obviousness has not been established, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

F. Claims 1 and 27

Claims 1 and 27 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Karger in view of U.S. patent 4,690,749 to Van Alstine *et al.* (herein referred to as Van Alstine). The applicants respectfully traverse.

As previously mentioned, independent claim 1 has been canceled without prejudice and without acquiescence. Dependent claim 27 now depends from independent claim 7.

Applicants assert that none of the references mention a device that is in a dry state capable of being rehydrated, or a device having a volume defining unit, mixing cavity, or waste cavity. If the Examiner continues to maintain that Karger and Van Alstine are the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in either Karger or Van Alstine. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Since both these references alone, or in combination, fail to teach or suggest all the limitations of dependent claim 27, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49). Therefore, the applicants respectfully request removal of this rejection.

G. Claim 1 and 30

Claims 1 and 30 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Regnier in view of Amigo. The applicants respectfully traverse.

As previously mentioned, independent claim 1 has been canceled without prejudice and without acquiescence. Dependent claim 30 now depends from independent claim 7. Applicants assert that none of the references mention a device that is in a dry state capable of being rehydrated, or a device having a volume defining unit, mixing cavity, or waste cavity. If the Examiner continues to maintain that Regnier and Amigo are the basis for this rejection, the Examiner is requested to make of record the passage relied upon, or state for the record that no such teaching can be found in either Regnier or Amigo. See, *In re Gartside*, 203 F.3d 1305, 53 USPQ2d 1769 (Fed. Cir. 2000).

Since both these references alone, or in combination, fail to teach or suggest all the limitations of dependent claim 30, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49). Therefore, the applicants respectfully request removal of this rejection.

H. Claims 44-46

Claims 44-46 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Deacher et al.

In order to advance the prosecution of this application, Applicants have canceled claims 44 and 46 without prejudice and without acquiescence. Thus, this rejection is now moot, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

Dependent claim 45 now depends from independent claim 7. Applicants assert that neither Amigo nor Deacher et al. mention all the limitations of claim 7 or dependent claim 45. Since both these references alone, or in combination, fail to teach or suggest all the limitations of dependent claim 45, the Examiner no longer demonstrates the necessary obviousness rejection criteria. (See *In re Hirao*, 535 F.2d 67; *Bausch & Lomb v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443, 447-49).

Thus, regarding dependent claim 45, if an independent claim is non-obvious under 35 U.S.C. 103(a), then any claim depending therefrom is by definition non-obvious. *In re Fine*, 5 USPQ 2d 2596 (Fed. Cir. 1988). Dependent claim 45 depends from independent claim 7 and, thus contains all the limitations of the independent claim and are non-obvious. Thus, a *prima facie* case of obviousness has not been established, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

I. Claim 50

Claim 50 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Karger.

In order to advance the prosecution of this application, Applicants have canceled claim 50 without prejudice and without acquiescence. Thus, this rejection is now moot, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.

J. Claim 51

Claim 51 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Amigo in view of Zimmer.

In order to advance the prosecution of this application, Applicants have canceled claim 51 without prejudice and without acquiescence. Thus, this rejection is now moot, and Applicants respectfully request that the 35 U.S.C. 103(a) rejection be withdrawn.


CONCLUSION

In view of the above amendment, applicant believes the pending application is in condition for allowance.

Applicant believes no fee is due with this response. However, if a fee is due, please charge our Deposit Account No. 06-2375, under Order No. HO-P02378US0 from which the undersigned is authorized to draw.

Dated: July 1, 2005

Respectfully submitted,

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